

Claims Rejection Under 35 USC § 112

Claims 15-17, and 27 are rejected under 35 USC § 112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims of the instant case are directed to a method of identifying compounds and the use of these compounds. Applicants asserted previously that the specification contains specific examples of compounds that fall within the Markush group claimed. The examiner in the final rejection maintains that it would require a large quantity of undue experimentation for the other compounds claimed.

Applicants argued in their reply to the first office action that although the compounds of the present invention may act upon other receptors, the invention of the present invention is that they are selective for VPAC receptor. While the examiner agreed with this reasoning, the examiner concluded that it would still require undue experimentation to determine their therapeutic effects and side effects. The Applicants respectfully disagree.

The compounds of the present invention are specific for VPAC receptors. This specificity for the VPAC receptors assures that side effects, if any, should be minimal. Further, Applicants disclose at page 31, lines 24-27 of the specification that animal models of skeletal muscle atrophy that are used for detecting the efficacy of a compound, may also be used for screening for toxicity and/or side effects to either muscles, other organs, or to the animal itself. In fact, Applicants point out that absence of side effects and toxicity could be a criterion by which further selection of a desirable compound could be made. Thus, it is the same screening assays that determine efficacy are also useful in determining side effects and potential toxicity of candidate compounds. Therefore, the Applicants believe that no undue experimentation is required in selecting a candidate compound, and request that the rejection be withdrawn.

Examiner further argues that other compounds, such as VIP, PAPAC-27, PVI, GHRH, secretin etc., may also increase muscle mass or function. Applicants agree that these compounds may act through VPAC receptors at certain concentrations, but these compounds do not exhibit specificity for VPAC receptors. It is well known in the art that these compounds bind other receptors as well (including those for GHRH, secretin, glucagons etc. (Laburthe et al., Ann. NY Acad Sci., vol. 527, pp. 296-313, 1988, see Fig. 9)) and thus lack the specificity for the VPAC receptors. Therefore, use of these promiscuous compounds could lead to toxicity, undesirable side effects, and overall unwanted physiological consequences. Applicants believe that the animal and in vitro models of muscle atrophy described in the specification would lead to choosing VPAC receptor specific candidate

compounds that will have the desirable effects of increasing muscle mass and/or function without toxicity or side effects. Therefore, Applicants believe that the rejection should be withdrawn.

Claims Rejection Under 35 USC § 102(b)

Claims 16, 17, and 27 stand rejected under 35 USC § 102(b) as being anticipated by Vittone et al., *Metabolism*, 46, 89-96 (1997). In reply to the first office action the Applicants argued:

The muscle results of Vittone et al. are not obtained by the interaction of a selective agonist with the VPAC receptor. The muscle effects are being obtained via another mechanism. The doses administered by Vittone et al. are probably not hitting the VIP1 receptor and definitely not hitting the VIP2 receptor. Therefore, Vittone et al. neither teaches nor suggests the role of VPAC receptors in muscle conditions.

In the final office action the examiner concluded, "Applicants assert that GHRH is selective for the VPAC receptors, therefore an argument that the rejection of Claims 16, 17, and 27 over Vittone et al. is improper contradicts this assertion." Applicants respectfully point out that this conclusion is incorrect. Applicants suggested that the doses administered by Vittone et al. would most definitely not act through the VPAC receptors. There was, in fact, implicit suggestion that these effects of GHRH are mediated by its interaction with other receptors. Furthermore, in her first office action, examiner stated that "In addition, helodermin, glucagon, GRF, secretin have their own specific receptors. For example, secretin, GRF, PHI and helodermin bind to the VIP receptor; VIP, GRF, PHI and helodermin bind to the secretion receptors (in pancreas and exocrine cells); glucagon binds to its receptors in the liver, and GRF to its receptors in the pituitary gland (Laburthe et al., *Ann. NY Acad Sci.*, vol. 527, pp. 296-313, 1988, see Fig. 9)." Therefore, it is well known in the art that GHRH binds to more than one receptors and any effect seen by its administration in Vittone et al. publication can not rightly be assigned to VPAC1 receptor binding. Applicants believe that these arguments are persuasive and the 35 USC § 102 (b) rejection in view of Vittone et al. should be withdrawn.

Claim 15 is being rejected under USC § 102(b) as being anticipated by Gourlet et al. (WO 98/02453). Applicants argued in response to the first office action that although Gourlet et al. teaches peptides that are highly selective for the VIP1 receptor, are agonists or antagonists, and pharmaceutical composition comprising the peptides and a pharmaceutically acceptable carrier; Gourlet et al. does not disclose pharmaceutical compositions for the treatment of muscle conditions. In the final office action, examiner replied "a recitation of the intended use of the claimed invention must result in a structural difference between the

claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making the intended use must result in a manipulative difference as compared to prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)."

Applicants respectfully traverse the Examiner's rejection of the claims in view of the Gourlet et al. MPEP section 2115 in part reads:

2115 Material or Article Worked Upon by Apparatus
MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT
APPARATUS CLAIMS

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d 966, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

In *In re Young*, a claim to a machine for making concrete beams included a limitation to the concrete reinforced members made by the machine as well as the structural elements of the machine itself. The court held that the inclusion of the article formed within the body of the claim did not, without more, make the claim patentable.

In *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967), an apparatus claim recited "[a] taping machine comprising a supporting structure, a brush attached to said supporting structure, said brush being formed with projecting bristles which terminate in free ends to collectively define a surface to which adhesive tape will detachably adhere, and means for providing relative motion between said brush and said supporting structure while said adhesive tape is adhered to said surface." An obviousness rejection was made over a reference to Kienzle which taught a machine for perforating sheets. The court upheld the rejection stating that "the references in claim 1 to adhesive tape handling do not expressly or impliedly require any particular structure in addition to that of Kienzle." The perforating device had the structure of the taping device as claimed, the difference was in the use of the device, and "the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself."

Note that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use. It does not apply to product claims or kit claims (i.e., claims directed to a plurality of articles grouped together as a kit).

Applicants respectfully suggest that this application of case law is incorrect. In *In re Casey*, the perforating device had the structure of the taping device, and that the device was performing essentially the same function. Thus, the structure used was the same; only the article or materials acted upon were different. In contrast, Gourlet et al. teaches the use of peptides that are selective for VIP1 receptor as a therapeutic agent in the treatment of bronchoconstrictive disorders, of tumors, and of myocardial infarctions and strokes, while the present invention teaches use of peptides that are selective for VPAC receptors in order to increase skeletal muscle mass or function. In fact, MPEP points out "Material or article worked upon does not limit apparatus claims" (subheading at MPEP section 2115). The apparatus/structure here are novel peptides that specifically bind to the VPAC receptors, which is the material or article worked upon. Thus, in the present case, the situation is the exactly opposite of *In re Casey*. The material worked upon is the same but the apparatus are different; and it is the apparatus (novel peptides) that the claim is drawn to. MPEP further states at the end of section 2115,

Note that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use.

Applicants believe that in the present application the structure/machinery/apparatus are different and are acting on same or similar material to achieve a novel result. Applicants respectfully submit that application of *In re Casey* is inappropriate here. This novel use for the peptides that are selective for VIP receptors has not been described before and is not obvious from disclosure in the Gourlet et al. Therefore, the use of the peptides that bind to VPAC receptors for treating skeletal muscle conditions is not inherent in Gourlet et al. Compounds that are specific for VPAC receptors may inherently have the property of increasing muscle mass or function, but this unrealized, novel use constitutes a patentable subject matter.

Applicants point to the following section of MPEP in support of their argument:

2112.02 Process Claims

PROCESS OF USE CLAIMS - NEW AND UNOBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive

analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

Applicants believe that they have discovered a novel use for the peptides that selectively bind VIP (=VPAC) receptors. This novel use is not obvious and has not been described in the prior art. In *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978), court found that the property of effecting analgesia was anticipated by prior art but that the property of nonaddictiveness was indeed unexpected. Similarly, in the present invention the property of these peptides as to effecting skeletal muscle mass or function is indeed unexpected and cannot be anticipated by Gourlet et al.

Applicants further submit that the issue of inherency which the Examiner has used to make the rejection is untenable in the light of *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977), wherein the claimed method of curbing appetite by administering certain adamantane compounds was found to be patentable over prior references that disclosed administering similar compounds to achieve antiviral effects in amounts encompassing the amounts intended and claimed by Shetty for appetite suppression. The PTO had held that the compounds used by Shetty are obvious over the references and the benefit of curbing appetite claimed by Shetty is inherent. The CCPA rejected the PTO's position and reversed the rejection of Shetty's method claims for curbing appetite, stating the following:

We cannot accept this conclusion. The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant's "amount effective to curb appetite" corresponds to or inheres in Narayanan's amount "to combat microbial infestation" does not persuade us of the obviousness of appellant's method. As this court said in *In re Naylor*, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966):

[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.

Finally, Applicants submit that it is well established that a novel, previously undisclosed use of a substance already suggested or known to be useful is patentable as a method of use under US patent law. While there are numerous examples, Applicants cite the granting of US 6,100,270 (to Pfizer) with method claims for a different medicinal use, i.e., treating male erectile dysfunction, for sildenafil compositions, which have previously been patented for the treatment of many conditions including angina, hypertension and congestive heart failure (US 5,250,534 and US 5,346,901). The method in this case involves the same method of oral administration of the compositions containing the active sildenafil. The new use is the basis for patentability of the method. As another example, claims to methods of treating male pattern baldness using minoxidil were patentable, even if minoxidil compositions had already been patented for treating hypertension. Further, claims to a process for obtaining increased meat, milk, egg or wool production in healthy animals comprising the administration of a minoxidil composition to a healthy animal were allowed. Again, methods of administering minoxidil for new uses were patentable.


The present method claims are likewise directed to a new or second use and are therefore patentable in accordance with US patent practice.

CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of the claims rejections under 35 USC § 112 and §102(b) and allowance of all application claims.

Respectfully submitted,

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